



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/521,805
Applicant : WOSIKOWSKI-BUTERS et al.
Filed : January 21, 2005
TC/A.U. : 1615
Examiner : Gollamudi S. Kishore
Confirmation No. : 3802
Docket No. : 2923-686
Customer No. : 6449

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

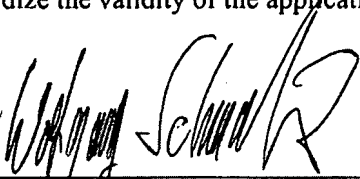
DECLARATION

I, Wolfgang Schmalix, declare as follows:

1. I am a co-inventor of the above-identified application.
2. I make this declaration in order to provide my opinion of the differences between the liposomal formulation of the above-identified application and the liposomal formulation of WO 00 04954.
3. WO 00 04954 discloses, but does not claim, that it is possible to incorporate amidino phenylalanine derivatives into the membranes of carrier vesicles (liposomes) for the purpose of facilitating the targeting of active substances.
4. From this limited disclosure regarding liposomal formulations in WO 00 04954, it is my opinion that one of skill in the art would recognize that the liposomal formulations disclosed therein, with amidino phenylalanine derivatives incorporated into the liposome membrane, would be for targeting lymphocytes. It is also my opinion that one of skill in the art would consider that the amidino phenylalanine derivatives, when incorporated into a liposome membrane, would be targeting agents and not active pharmaceutical ingredients. WO 00 04954 discloses that

active pharmaceutical ingredients, such as doxorubicin, are encapsulated in the liposomes. In the above-identified application, it is not necessary to have other active pharmaceutical ingredients encapsulated. In the above-identified application, the guanidino and amidino phenylalanine derivatives are the active pharmaceutical ingredients, and the guanidino or amidino phenylalanine derivatives are encapsulated by a liposome. Furthermore, there is no reason why one of skill in the art considering the disclosure of WO 00 04954 would encapsulate the guanidino and amidino phenylalanine derivatives of the above-identified application, as that would defeat the desired targeting function.

5. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. All statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Wolfgang Schmalix

16. Oct 2007

Date